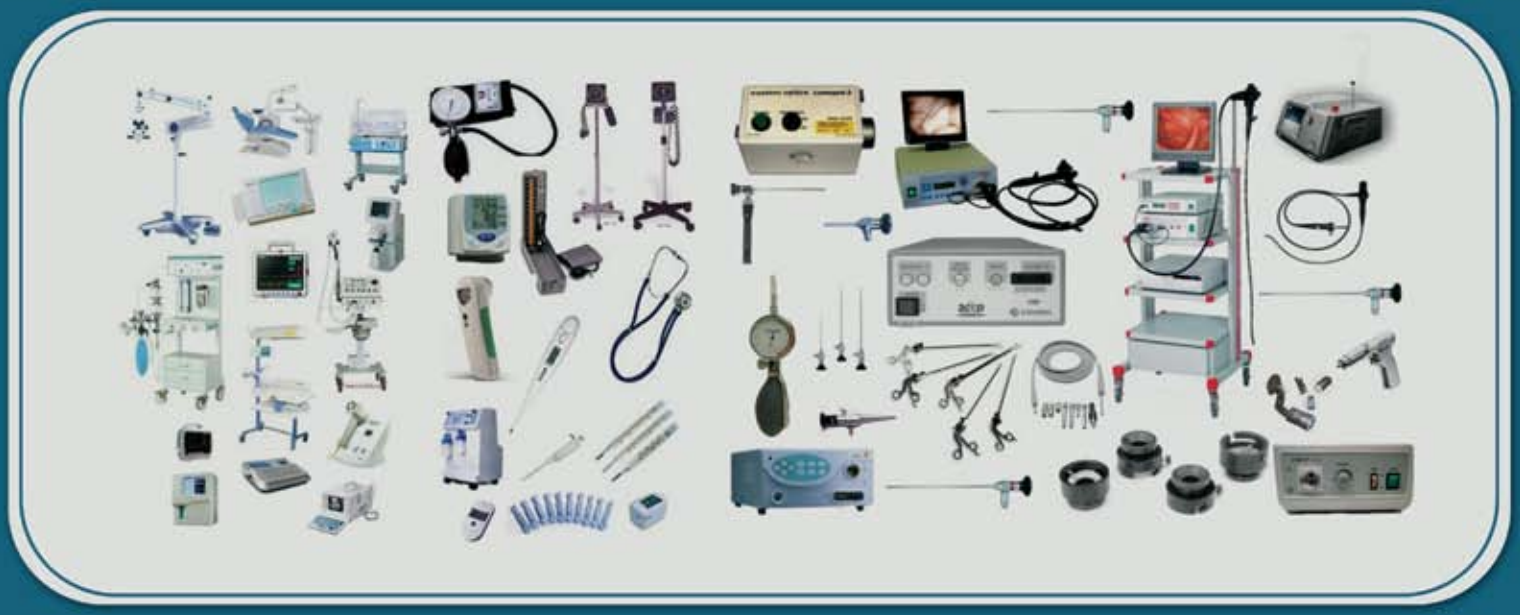
सत्यमेव जयते

NATIONAL HEALTH MISSION
राष्ट्रीय स्वास्थ्य मिशन

Ministry of Health and Family Welfare
Government of India



Technical Specifications of Medical Devices for **Special Neonatal Care Unit**

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सचिव
B.P. SHARMA
Secretary

सत्यमेव जयते

भारत सरकार
स्वास्थ्य एवं परिवार कल्याण विभाग
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
Government of India
Department of Health and Family Welfare
Ministry of Health and Family Welfare

Dated : 29th April, 2015

MESSAGE

Ministry of Health and Family Welfare in its endeavor to achieve highest standards of health for the people has undertaken several programmatic and institutional strengthening measures. National Health Mission is one such programmatic intervention aimed at improved overall health with special focus in energizing rural health infrastructure and services. Providing essential medical equipment is a critical component of strengthening health infrastructure. However, rapidly changing technologies, complexity associated with medical equipment and high costs of procurement - all these make selection of appropriate and cost effective equipment a challenging task. I am happy to note that National Health Systems Resource Centre (NHSRC) under the guidance of experts and with active participation of stakeholders have developed technical specifications of commonly procured medical devices to facilitate procurements by State / UT Governments. I am sure that you will find these very helpful. The specifications are suggestive and we have tried to keep them generic. However, we would welcome any suggestions for further improvement in these specifications.

(B.P. Sharma)

कमरा नं 156, ए-स्कंध, निर्माण भवन, नई दिल्ली-110011
Room No. 156, A-Wing, Nirman Bhawan, New Delhi-110011
Tele : (O) 011-23061863, Fax : 011-23061252, E-mail : secyhfw@gmail.com

NATIONAL HEALTH MISSION
राष्ट्रीय स्वास्थ्य मिशन

C.K. Mishra, IAS
Additional Secretary &
Mission Director, NHM
Telefax : 23061066, 23063809
E-mail : asmd-mohfw@nic.in

भारत सरकार
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
निर्माण भवन, नई दिल्ली - 110011
GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
NIRMAN BHAVAN, NEW DELHI-110011

MESSAGE

Under National Health Mission, support is being provided to all States/UTs for improving quality of health services and improving necessary infrastructure including medical equipment. Providing for adequate, safe and appropriate medical equipment at all levels of public health facilities remains a focus for the Government. Given the challenges of procurement it is necessary to have generic specifications for medical equipment. Cost, utility, availability in domestic market, maintenance and patient safety are crucial issues to be considered while procuring medical devices. I am pleased to note that these have been adequately considered by NHSRC while preparing the specifications. Keeping them as reference specifications while undertaking procurement will reduce costs of procurement, maintenance problems and procurement lead time. I am happy to note that NHSRC, has filled in an important technical gap by providing these specifications and I am sure that technical specifications suggested here will serve as a reference for procurement of medical devices under the National Health Mission.

We would be happy to have your valuable suggestion on improving these.

(C.K. Mishra)

New Delhi
29th April, 2015

NATIONAL HEALTH MISSION
राष्ट्रीय स्वास्थ्य मिशन

Manoj Jhalani, IAS
Joint Secretary
Telefax : 23063687
E-mail : manoj.jhalani@nic.in

भारत सरकार
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
निर्माण भवन, नई दिल्ली – 110011
GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
NIRMAN BHAVAN, NEW DELHI - 110011

31st April 2015

MESSAGE

National Health Systems Resource Centre which is also a WHO collaborating centre for priority medical devices & health technology policy; in consultation with users, care providers, engineers, medical technologists and representatives from medical devices manufacturers association has formulated technical specifications for commonly used medical devices. Specifications are suggestive in nature and any specific requirement needs to be incorporated at the time of procurement. However having well deliberated specification at one place should considerably reduce the procurement cost & time and improve quality of procurement.extensively. The specifications suggested herein are an outcome of several rounds of consultations with experts, user clinicians & care providers, medical technologists & engineers and industry stake holders. While effort has been made to make the specifications as generic as possible and consensus and technical appropriateness has been the corner stone of this technical exercise. We would welcome suggestions from the States.

(Manoj Jhalani)

Acknowledgement

Medical devices are a very important part of health care and their use is increasing by the day. Technical specifications play an important role in identification, selection and procurement of appropriate and cost effective medical devices. Consistency and standardization in technical specifications promotes positive competition and reduces effective costs. It also promotes uniformity in user training and smooth maintenance of equipment. In order to address the variation in technologies many of which could be add-ons, separate exercises were undertaken for specific categories of medical devices procured under National Health Mission. The experts consulted for specifications formulation exercises included clinicians, medical technologists, maintenance experts and also representatives from manufactures' industry associations. Specifications for medical devices for Special Neonatal Care Units, Neonatal and Pediatric Care Units, Ambulances, Operation Theatre for district sub-district levels, Rashtriya Bal Suraksha Karyakaram, Laboratory & Radiology equipment, Skill laboratory program are an outcome of intense participation, deliberation, technical research and inputs from experts. These include experts from prestigious institutions such as AIIMS, PGIMER-Chandigarh, RML Hospital, Safdarjung Hospital, Sree Chitra Institute of Medical Sciences & Technology, Central Scientific Instrument Organisation, Hindustan Life Care Limited, IITs, to name a few. Overall review by DGHS provided further validation to the technical work. Division of Healthcare Technology, NHSRC being the technical secretariat for this work played a pivotal role and names of following professionals deserve special mention: Jitendar Sharma, Mohammad Ameel, Anurag, Swati Barwala, Prabhat Arora, Kavita Kachroo, Akriti Chahar, Pankaj Parashar, Prashant Tiwari, Ashfaq Ashraf and Anjanaya. I am sure that specifications confirming to adequate standards of safety and accuracy shall be immensely useful for the states in undertaking appropriate and cost effective procurement of medical devices.

Dr. Sanjiv Kumar
Executive Director

RADIANT WARMER

Version no. :		2.0
Date:		13/08/2013
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Infant warmer
GMDN code(s)		CT1452
GMDN category		04 Electro mechanical medical devices
Definition		Mains electricity (AC-powered) mobile device that contains an infrared (IR) heating element(s) designed to emit controlled, evenly distributed overhead heat to the body of a newborn/infant patient requiring supplemental heat. This device is equipped with wheels so that it can easily be moved to different areas of a room, ward, or department.
GENERAL		
1. USE		
1.1	**Clinical purpose**	Infant Radiant warmer is an electrically powered device with a radiant heating source intended to maintain the thermal balance of an infant by direct radiant of energy in the infrared region of the electromagnetic spectrum.
1.2	**Used by clinical department/ ward**	Neonatal ICU/ SNCU
1.3	**Overview of functional requirements**	Radiant warmer is a microprocessor controlled unit with heater placed on the over head panel. This work on both servo and manual mode options to maintain the baby temperature at the set value. There are two modes of operation manual and baby control or skin control (servo) mode. It has Digital displays reading of the set and baby observed temperatures seperately.
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. It should be microcontroller based radiant warmer with manual and servo options. 2. It should have facility to display skin set, skin observed temperature in degree C and heat power separately. 3. Should have user friendly touch panel control. 4. It should have ceramic or quartz infrared or calrod heater. 5. It should have audiovisual alarm facility for overheating beyond set temperature range. 6. It should have alarm facility for patient temperature less than or greater than the required temperature i.e. above or below the set range.Machine should sense the skin probe failure and cut off the heater. 7. Warmer head should be rotatable in different direction, so as to allow taking X-ray. 8. It should have alarm for probe failure,power failure, system failure and heater failure.

		9. Observation light of 90 to 100 foot candles or 1000 Lux (color temperature range 3700K to 5100K) sould be provided for inspection. 10. Battery back up for Power failure indication during power fail. 11. The desired temperature range from 25 to 40 degree C and settable temperature can be from 32 to 38°C. 12. The resolution should be 0.1 degree C and accuracy should be 0.2 °C. 13. Should have a facility to lock the keyboard to avoid unwanted user modification of the set parameters. 14. The height of the warmer should be adjustable for different types of bed. 15. It should have separate bassinet trolley, bed should be tiltable and have provision for x-ray cassette holder, Mattress foam density should be minimum 25 kg/cm3, transparent collapsible side walls easily detachable for cleaning. Mattress size should be minimum 20"X30". 16. Should have a Feather Touch operation with large digital display and comprehensive alarms. Control Panel should be liquid proof and allow easy and hygienic disinfection. 17. Manual Mode can adjust Heater Output 10 -100 %, with 10% increment, an auditory and visual alarm shall be given at least every 15 min. 18. In manual mode, heater cut off / switch off , if the maximum irradiance at any point of the mattress area exceeds a total irradiance level of 10 mW/ cm2 (between 10 to 30 minutes). 19. Bed should be about 80 - 100 cms from the Floor and 80-90cms from the heat source. 20. should have lockable castor wheels. 21. Green indicator light shall be provided to indicate that warmer is ready for normal use.
		22. Markings on the bassinet and X-Ray cassette holder is mandatory to enable proper positioning of the baby while doing the X-Ray. 23. The size of the drop down sides should be such that it is 5" above the mattress surface and should be atleast 6mm thick; clear and transparent. 24. If there is more than 60% heater output for 10 minutes it should cutoff with alarm. 25. For the purpose of cable management there should be atleast two number of tubing ports (edges covered by silicon rings) on the side walls.The height of the side walls should be minimum 110mm over the mattress. 26. X-Ray cassettte tray should be atleast 750X350mm and should adopt upto 20mm thick X-Ray cassette. 27. Th bay bed should be crevice free for ease of cleaning, infection control. 28. The mattress used should be of biocompatible material. 29. Skin temperature probe should be small in size not more than 10mm diameter and 3-4mm thick to fix the probe firmly on the infant. Baby contact material should be biocompatible as per ISO 10993 standard requirement. It should be insulated on one side and have well conducting non-rusting, non reacting metallic surface on the other side. Probe wire should be pliable, thin and soft. The attachment site of the probe with the wire should also be pliable and non stiff.
2.2	**Settings**	1. Should have Manual mode and Baby (Servo) mode settings. 2. Mode of operation should be clearly displayed. 3. In servo mode baby set temperatrue should be 32 to 38° C.
2.3	**User's interface**	Manual and Servo controlled temperature regulation.

2.4	**Software and/or standard of communication(where ever required)**	LED Display and inbuilt software; Interruption and restoration of the power supply does not change the preset values.
2.5	**Others**	1. Devcie shall not overbalance when placed in any transport position of normal use on a 10° inclined plane from the horizontal plane. 2. Transformers of devcie shall be protected against overheating in the event of short circuit or overload of any output winding. 3. Patient leakage current should be less than 100 µA in normal condition 4. Temperature on the baby mattress should not exceed 43 deg C when the warmer is operating under steady temperature condition. 5. Temperature of HEATER GUARDS should not exceed 85 °C in normal use. 6. The Temperature differences on the mattress shall not exceed 2 °C.
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	specifications upto: 2000 mm (Height) X 900mm (Width) X 1100 mm (Length).
3.2	**Weight (lbs, kg)**	maximum spec: 150kg.
3.3	**Configuration**	Atleast 60 degree angle adjustment must be possible in the heat source and it should provide shielding to the infant in case of breakage of tubes/bulbs, All surfaces to be made of corrosion resistant material.
3.4	**Noise (in dBA)**	Auditory alarm shall have a sound level of at least 65 dBA at a distance of 3 m from the front of the infant radiant warmer, and the sound level of the alarm shall not exceed 80 dBA on the mattress.
3.5	**heat dissipation**	Should maintain upto 36.5 deg temp and the heat disbursed through a exhaust fan , so that effect of UV light is not disturbed.
3.6	**Mobility, portability**	Yes, on castors (2 of the castors should have breaks; casotor size can be atleast 4inch).
4. ENERGY SOURCE (Electricity, UPS, Solar, Gas, Water, CO_2 ....)		
4.1	**Power Requirements**	220 to 240V, 50 Hz
4.2	**Battery operated**	Power failure indication during power fail.
4.3	**Tolerance (to variations, shutdowns)**	± 10% of input
4.4	**Protection**	OVP, earth leakage protection
4.5	**Power consumption**	maximum 800 Watt
4.6	**Other energy supplies**	Solar Heating - desirable ; not essential.
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories (mandatory, standard, optional)**	Should have standard IV pole(sturdy;non rusting; medical grade stainless steel;adjustable to a max height of 6 feet from the ground level), monitor tray(12X10 inches;270 deg swivel;fixed at level of warmer display) and storage trays.
5.2	**Spare parts (main ones)**	Skin temperature probes.
5.3	**Consumables / reagents (open, closed system)**	Thermal refelctor to fix the skin probe on baby.
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Operating condition: – Capable of operating continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90% in ideal circumstances. – an ambient air velocity is less than 0.3 m/s.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Complete unit to be easily washable and sterilizable using both alcohol and chlorine agents.

	7. STANDARDS AND SAFETY	
7.1	**Performance and safety standards (specific to the device type);Certificates (pre-market, sanitary, ..); Local and/ or international**	Should be FDA / (CE of class IIb) approved product. Shall meet IEC-60601-1-2:2007 Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (Or Equivalent BIS). Shall neet IEC 60601-2-21: 2009 Medical Electrical Equipment – Part 2-21: Particular Requirement for the basic safety and essential performance of infant radiant warmers . should meet IEC 60601-1:2005 standard requirements. Baby contact material should be biocompatible as per ISO 10993 standard requirement. Manufacturer should be ISO 13485 certified.
	8. TRAINING AND INSTALLATION	
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	Availability of 5 amp/15 Amp. Electrical socket (2 nos) for each warmer.
8.2	**Requirements for sign-off**	Certificate of Calibration and inspection from the factory.
8.3	**Training of staff (medical, paramedical, technicians)**	user training manual required.
8.4	**Others**	List of important spare parts and accessories with their part number and costing.
	9. WARRANTY AND MAINTENANCE	
9.1	**Warranty**	nickel chrome wire filament and tube of quartz should have a life time warranty; equipment - 3 years.
9.2	**Maintenance tasks**	maintainance manual detailing complete maintaining schedule.
9.3	**Service contract clauses, including prices**	warranty of one year with free servicing (min. 3) during warranty.
9.4	**Others**	The spare price list of all spares and accessories (including minor) required for maintenance and repairs in future after guarantee / warranty period should be attached.
	10,. DOCUMENTATION	
10.1	**Operating manuals, service manuals, other manuals**	to be supplied.
10.2	**Other accompanying documents**	User/Technical/Maintenance manuals to be supplied in English.
	11. NOTES	
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/landline number)**	should provide complete contact details of sales and service departments.
11.2	**Recommendations or warnings**	Any warning/ precautions to be declared.

BASINET

Version no. :		2.0
Date:		13/08/13
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Bed, Infant, general purpose.
GMDN code(s)		CT 1469
Definition		A bed or crib designed for new born babies. It is ususally opened rectangular receptacle and mounted on a wheeled frame work (trolley). It is padded or lined with appropriate bedding and used mostly as the general purpose or standard baby bed in berthing departments. Source of additional heating can be provided to the new born.
GENERAL		
1. USE		
1.1	**Clinical purpose**	For care of neonate as a body positioning device.
1.2	**Used by clinical department/ ward**	NICU/SNCU, labour room, maternity ward.
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	Baby Tray with mattress, along with head up/down facility, Mattress density approx 25Kg/m3 and with removable, washable, waterproof cover, mattress cover should be biocompatible and easy to clean. Lower Shelf which is rotatble and swivel castors (100mm) - 2 castors with brake. Baby tray should be of polycarbonate material. It should not topple on 10 deg inclined plane. Baby bed should withstand upto 10kg weight. It should have provision for baby name identification tag/label. Minimum dimensions of the bassinet mattress should be 20X30" and walls both for the radiant warmer and baby bassinet.
2.2	**Settings**	NA
2.3	**User's interface**	Care giver should have a clean view of the neonate inside the basinet.
2.4	**Software and/or standard of communication(where ever required)**	NA
2.5	**Others**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	90cm-100cm height, 40cm-70cm width, 70-80cm length.
3.2	**Weight (lbs, kg)**	net weight: 30 kgs with loading capacity to be 10 kg.
3.3	**Configuration**	NA
3.4	**Noise (in dBA)**	NA
3.5	**heat dissipation**	NA
3.6	**Mobility, portability**	Yes, on castors
4. ENERGY SOURCE (Electricity, UPS, Solar, Gas, Water, CO_2 ....)		
4.1	**Power Requirements**	NA
4.2	**Battery operated**	NA

4.3	**Tolerance (to variations, shutdowns)**	NA
4.4	**Protection**	NA
4.5	**Power consumption**	NA
4.6	**Other energy supplies**	NA
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories (mandatory, standard, optional)**	mattress
5.2	**Spare parts (main ones)**	castors
5.3	**Consumables / reagents (open, closed system)**	NA
5.4	**Others**	NA
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Operating condition: –Capable of operating continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90% in ideal circumstances. – an ambient air velocity is less than 0.3 m/s.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Complete unit to be easily washable using both alcohol and chlorine agents.
	7. STANDARDS AND SAFETY	
7.1	**Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type); Local and/or international**	ISO 13485 and CE certified
	8. TRAINING AND INSTALLATION	
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	NA
8.2	**Requirements for sign-off**	NA
8.3	**Training of staff (medical, paramedical, technicians)**	NA
8.4	**Others**	NA
	9. WARRANTY AND MAINTENANCE	
9.1	**Warranty**	3 year
9.2	**Maintenance tasks**	
9.3	**Service contract clauses, including prices**	warranty of one year with free servicing (min. 3) during warranty.
9.4	**Others**	
	10. DOCUMENTATION	
10.1	**Operating manuals, service manuals, other manuals**	NA
10.2	**Other accompanying documents**	List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.
10.3	**Recommendations for maintenance**	washing periodically
10.4	**Others**	Na
	11. NOTES	
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/landline number)**	
11.2	**Recommendations or warnings**	

PHOTOTHERAPY

Version no. :		2.0
Date:		13/08/13
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Phototherapy units/systems.
GMDN code(s)		CT 2066
Definition		A neonatal phototherapy unit is a device used to treat or prevent hyperbilirubinemia (elevated serum bilirubin level). The device consists of one or more lamps that emit a specific spectral band of light, under which an infant is placed for therapy.
GENERAL		
1. USE		
1.1	**Clinical purpose**	Emits in the main radiation spectrum in the range between 400 nm and 550 nm for reducing the concentration of Bilirubin.
1.2	**Used by clinical department/ ward**	New born stablisation unit, SNCU.
1.3	**Overview of functional requirements**	a) Provides filtered light using radiant electric lights, not fibreoptics. b) Infant supported securely in bassinette below bulbs. c) Monitors hours of radiant light exposure.
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. Phototherapy should be based on CFL tube/LED technology, which after filtering should provide, a light of wavelength approximately 450 to 470 nm with peak wavelength of 450-460nm range. 2. Irradiance to be minimum 35 µW/cm2/nm at 40 cm height and UV should not exceed 10-4 W/m2 in 180nm to 400nm. 3. Digital Hour meter showing total exposure time for current patient to be clearly visible by operator. 4. Effective light field >700 cm2. 5. Lamp life should be minimum 20000 hours in case of LED and 1000 hours in case of CFL and should have timer to indicate its usage. 6. Over temperature safety cut out to be included. 7. Up, down and tilting of head should be possible. 8. The unit should be mounted with castor wheels with brakes. 9. Variation in intensity over 5-6 hours < 10%. 10. The irradiance ratio (min to max) shall be greater than 40 % on mattress. 11. Green indicator light shall be provided to indicate that equipment is ready for normal use. 12. Interruption and a restoration of the power supply do not change preset values. CFL/LED heat can be reduced by natural cooling. 13. CFL/LED should be protectred from free fall. 14. It should not topple on 10 deg inclined angle. 15. The temperature of baby bed and metal surfaces should not exceed 40deg C and 43 deg C for other accesible surfaces.

		16. There should be intutive method to indicate the light surface is at the appropriate treatment distance. 17. Mobile stand with movable castors and height adjustment facility along with easy swivelling of source box. Unit can be used along with Infant care trolley, Radiant Warmer and Incubator.
2.2	**Settings**	UP/DOWN adjustment of Over Head Unit; The phototherapy unit should be able to provide effective treatment for beds and incubators of varying heights (generally 1.0 to 1.6m). Adjustment of light intensity may be provided.
2.3	**User's interface**	Manual
2.4	**Software and/or standard of communication(where ever required)**	LED Display and inbuilt software
2.5	**Others**	
	3. PHYSICAL CHARACTERISTICS	
3.1	**Dimensions (metric)**	minimum spec: 1650mm Height X 750mm Width X 500mm Length.
3.2	**Weight (lbs, kg)**	<20 kg
3.3	**Configuration**	Clear cabinet for observation of infant. Infant bassinette to be an integral unit which should be detachable. Unit to provide shielding of infant in the event of bulb breakage. Bulb mount to have angle adjustment of at least 30 degrees. All surfaces to be made of corrosion resistant materials. Light unit tilting facility and height adjustment facility.
3.4	**Noise (in dBA)**	<60dBA
3.5	**heat dissipation**	The temperature of baby bed and metal surfaces should not exceed 40deg C and 43 deg C for other accesible surfaces.
3.6	**Mobility, portability**	Minimum 3 castors and atleast 2 with brakes.
	4. ENERGY SOURCE (Electricity, UPS, Solar, Gas, Water, CO_2 ....)	
4.1	**Power Requirements**	220 to 240V, 50 Hz
4.2	**Battery operated**	NA
4.3	**Tolerance (to variations, shutdowns)**	± 10% of input AC
4.4	**Protection**	Electrical protection by resettable overcurrent breakers or replaceable fuses, fitted in both live and neutral lines.
4.5	**Power consumption**	Should not be more than 160 W.
4.6	**Other energy supplies**	Mains cable to be at least 2.5m length.
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories (mandatory, standard, optional)**	Complete set of replacement tubes to allow 3 months' continuous operation Two replacement sets of fuses, if replaceable type used.
5.2	**Spare parts (main ones)**	No spares required.
5.3	**Consumables / reagents (open, closed system)**	Total 500 nos. Infant eye masks of both available sizes (term and pre term babies).
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Complete unit to be easily washable and sterilizable using both alcohol and chlorine agents.

7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary, ..);Performance and safety standards (specific to the device type);Local and/or international**	Should be FDA / CE approved product. Shall meet IEC-60601-1-2:2007 Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (Or Equivalent BIS). Should meet IEC 60601-1:2005 standard requirements. Shall neet IEC 60601-2-50: 2009 Medical Electrical Equipment – Part 2-50: Particular Requirement for the basic safety and essential performance of infant phototherapy equipment. Manufacturer should be ISO 13485 certified.
8. TRAINING AND INSTALLATION		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	Supplier to perform installation, safety and operation checks before handover.
8.2	**Requirements for sign-off**	Certificate of Calibration and inspection from the factory.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided.
8.4	**Others**	
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	3 years for the machine and 20,000 hours for LEDs/ 1000 hours for CFL.
9.2	**Maintenance tasks**	maintainance manual detailing complete maintaining schedule.
9.3	**Service contract clauses, including prices**	Local clinical staff to affirm completion of installation.
9.4	**Others**	
10. DOCUMENTATION		
10.1	**Operating manuals, service manuals, other manuals**	Advanced maintenance tasks required shall be documented. User, technical and maintenance manuals to be supplied in english language. List to be provided of equipment and procedures required for local calibration and routine maintenance.
10.2	**Other accompanying documents**	List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.
11. NOTES		
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations or warnings**	List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.

IRRADIANCE METER

Version no. :		2.0
Date:		13/08/13
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Blue light radiometer
GMDN code(s)		NA
Definition		An instrument designed to measure the radiant flux (radiant power) in the spectral range of 400 to 500 nm (i.e., blue) during bilirubinemia treatment for newborns and infants. It typically includes a pre-filter intended to remove wavelengths of light not in the 400-500 nm range (e.g., infrared light); a primary detector consisting of a temperature-stabilized, solid-state [e.g., selenium (Se) or indium-gallium-arsenide] device used to detect radiation; electronic circuits including an amplifier and a electric meter; a power source (e.g., a battery); and a display showing the results either in analogue or digital format.
GENERAL		
1. USE		
1.1	**Clinical purpose**	used for checking raddiance of phototherapy units
1.2	**Used by clinical department/ward**	New born stablisation unit, SNCU
1.3	**Overview of functional requirements**	
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. Hand held, Band pass filter with max transmission 425-475 nm. 2. Light detector sensititivity range: 0-2000 µW/cm^2/nm. 3. Measurement range: 0-100 µW/cm^2/nm. 4. Minimal graduation: 1µW/cm^2/nm. 5. Accuracy: ± 10%. 6. LED or LCD display. 7. Should be able to zero between measurements. 8. Fast measurement response- <5 sec. 9. Memory storage: required. 10. UV and IR should be blocked. 11. Hold function.
2.2	**Settings**	NA
2.4	**User's interface**	Digital display

2.5	**Software and/or standard of communication(where ever required)**	Built in software
2.6	**Others**	
	3. PHYSICAL CHARACTERISTICS	
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Configuration**	NA
3.4	**Noise (in dBA)**	NA
3.5	**heat dissipation**	NA
3.6	**Mobility, portability**	Mobile
	4. ENERGY SOURCE (Electricity, UPS, Solar, Gas, Water, CO_2 ....)	
4.1	**Power Requirements**	220V/ 50 Hz
4.2	**Battery operated**	in built
4.3	**Tolerance (to variations, shutdowns)**	NA
4.4	**Protection**	Should be provided with fuse while using mains for charging.
4.5	**Power consumption**	30W max
4.6	**Other energy supplies**	NA
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories (mandatory, standard, optional)**	Charger
5.2	**Spare parts (main ones)**	No spares
5.3	**Consumables / reagents (open, closed system)**	NA
5.4	**Others**	
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	NA
	7. STANDARDS AND SAFETY	
7.1	**Certificates (pre-market, sanitary, ..);Performance and safety standards (specific to the device type);Local and/or international**	Shall meet IEC-61010(Or Equivalent BIS) Standard Reuirements. Should be FDA / CE approved product; ISO certified company.
	8. TRAINING AND INSTALLATION	
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	NA
8.2	**Requirements for sign-off**	Hand-over report with end user sign.
8.3	**Training of staff (medical, paramedical, technicians)**	user training on complete operation should be provided
8.4	**Others**	

9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	3 yrs
9.2	**Maintenance tasks**	calibration to be done atleast once a year.
9.3	**Service contract clauses, including prices**	Two Preventive Maintainance annually under the warranty period.
9.4	**Others**	
10. DOCUMENTATION		
10.1	**Operating manuals, service manuals, other manuals**	operator & service manual with circuit diagram should be provided with the machine.
10.2	**Other accompanying documents**	calbration certification to be attached with the instalation report.
10.3	**Recommendations for maintenance**	NA
10.4	**Others**	
11. NOTES		
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/ landline number)**	
11.2	**Recommendations or warnings**	

SELF INFLATING RESERVOIR BAG

Version no. :		1.0
Date:		13/08/13
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Manual pulmonary resuscitator, reusable.
GMDN code(s)		CT1911
Definition		A hand-operated device designed to provide or assist ventilation in patients who are apnoeic or exhibit inadequate respiration. It typically employs entrained ambient air and includes a large flexible chamber that is hand-ventilated, a gas reservoir, tubing, and a connector for attachment to a mask or endotracheal (ET) tube; oxygen (O2) from an O2 source may also be connected when necessary. It is used by emergency medical services (EMS) in ambulances, intensive care units (ICU), during internal patient transfer, accident and emergency (A&E), mass casualty incidents (MCI), and is generally placed strategically throughout a hospital. This is a reusable device.
GENERAL		
1.USE		
1.1	**Clinical purpose**	to provide or assist ventilation in a patient who is apnoeic or exhibits inadequate respiration through manual pulmonar-driven pressure cycle functions.
1.2	**Used by clinical department/ward**	It is used in ambulances, intensive care units (ICU), during internal patient transfer, accident and emergency (A&E), and mass casualty incidents (MCI).
1.4	**Overview of functional requirements**	
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics**	1. Manual resuscitator with transparent face-mask. 2. Child models (750ml, 500ml and 260ml bag capacity). 3. Standard 15-22 mm Swivel connector allows connections to all common masks Endotracheal Tubes. 4. Provision to give supplemented oxygen-by-oxygen reservoir providing 100% oxygen. 5. Non-re breathing valve enabling the patient to inspire oxygen from the reservoir bag. 6. Should be single hand operatable. 7. should be easy to dissamble for cleaning and disinfection. 8. Should have pressure release valve at 40cm H2O. 9. Should have silicone oxygen tube 2m length. 10. It should be upto 40 times autoclavable including bag and washers. 11. The bag should be of silicone material. 12. Self Inflating Resuscitator bag should be of medical grade silicone rubber. 13. The reservoir should be a PVC bag of 600ml capacity for 260ml & 500ml bag capacity and 1000ml for 750ml bag capacity.

2.2	**Settings**	flow rates, ventilation, airway pressure
2.3	**User's interface**	Manual
2.4	**Software and/or standard of communication(where ever required)**	NA
	3. PHYSICAL CHARACTERISTICS	
3.1	**Dimensions (metric)**	Hanheld
3.2	**Weight (lbs, kg)**	Light enough to be operated by hand/palm for long duration.
3.3	**Configuration**	NA
3.4	**Noise (in dBA), heat dissipation**	NA
3.5	**Mobility, portability**	Hanheld
3.6	**Others**	
	4. ENERGY SOURCE (Electricity, UPS, Solar, Gas, Water, CO_2 ....)	
4.1	**Power Requirements**	NA
4.2	**Battery operated**	NA
4.3	**Tolerance (to variations, shutdowns)**	NA
4.4	**Protection**	NA
4.5	**Power consumption**	NA
4.6	**Other energy supplies**	NA
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories (mandatory, standard, optional)**	Silicon bellow, Non Rebreathing Valve, 2 meter oxygen tube, Guedel Airway.
5.2	**Spare parts (main ones)**	Oxygen Reservoir bag.
5.3	**Consumables / reagents (open, closed system)**	Neonatal Mask of 3 sizes viz 00, 0 and 1.
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Operating condition: –Capable of operating continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90% in ideal circumstances. – an ambient air velocity is less than 0.3 m/s.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Complete unit to be easily washable and sterilizable using both alcohol and chlorine agents.
	7. STANDARDS AND SAFETY	
7.1	**Certificates (pre-market, sanitary, ..);Performance and safety standards (specific to the device type); Local and/or international**	ISO 13485;Manufacturer / supplier should have ISO certificate for quality standard. Should be FDA / CE approved product or BIS certified Should meet ISO 10651-4 standard requirement.
	8. TRAINING AND INSTALLATION	
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	Supplier to perform installation, safety and operation checks before handover.
8.2	**Requirements for sign-off**	Certificate of Calibration and inspection from the factory.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided.

9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	1 year.
9.2	**Maintenance tasks**	Maintainance manual detailing complete maintaining schedule.
9.3	**Service contract clauses, including prices**	
9.4	**Others**	
10. DOCUMENTATION		
10.1	**Operating manuals, service manuals, other manuals**	Required
10.2	**Other accompanying documents**	Demonstration CDs
10.3	**Recommendations for maintenance**	NA
11. NOTES		
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/ landline number)**	NA
11.2	**Recommendations or warnings**	NA

LARYNGOSCOPE

Version no. :		2.0
Date:		13/08/13
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Laryngoscopes
GMDN code(s)		CT 1723
Definition		A hand-held device (i.e., non-endoscopic rigid type) intended to be used by anaesthesia/emergency service personnel to manipulate the tongue, preventing it from obstructing the oropharynx and enabling a clear view of the trachea for the insertion of an endotracheal (ET) tube prior to the delivery of inhalation anaesthesia and/or ventilation. It has a handle containing batteries to power its light (a small built-in light bulb or fibreoptic light) for airway illumination, and a curved or straight blade of various designs and lengths that can be hinged/ interchanged or integral. Some types can be magnetic resonance imaging (MRI) compatible. This is a reusable device to access respiratory status of a patient, and to help in the treatment evaluation of patients suffering from chronic respiratory and /or acutedisorders (e.g., asthma, emphysema).
GENERAL		
1. USE		
1.1	**Clinical purpose**	For viewing vocal folds and glottis. Surgical and mechanical ventilation/ intubation.
1.2	**Used by clinical department/ward**	O.T / ICU / NICU/ Casuiality
1.3	**Overview of functional requirements**	A light source on or via the blade illuminates the larynx to allow viewing and tube passage. The unit is handheld with internal batteries and has interchangeable, rigid blades of different sizes.
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	Fiber optic Laryngoscope- preferably should be single patient use to ensure no infection to the patients, should comprise of disposable handle and reusable light source using the latest LED technology. The main body of the handle should incorporate an excellent grip & should feel even wearing a glove. There should be a freely moving light intensifier of light from the light source through to the tip of the fiber optic blade to prevent any possibility of cross contamination. The unit should allow the blade to be inserted easily & should provide a positive locking mechanism when moved in to the closed position. The patient contact material should be biocompatible.
2.2	**Settings**	NA
2.3	**User's interface**	Manual
2.4	**Software and/or standard of communication(where ever required)**	NA

3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	Light weight
3.3	**Configuration**	1. Handheld unit, single piece when in use. 2. On/off switch to be robust and easy to use. 3. External material to be non-ferrous. 4. Blades to be surgical grade stainless steel. 5. Supplied in protective, reclosable container.
3.4	**Noise (in dBA), heat dissipation**	NA
3.5	**Mobility, portability**	Yes
3.6	**Others**	storage box should be provided
4. ENERGY SOURCE (Electricity, UPS, Solar, Gas, Water, CO_2 ....)		
4.1	**Power Requirements**	independent of external source.
4.2	**Battery operated**	Internal batteries, rechargeable preferred/ Penlight battery AA size, Battery charger (if rechargeables), Battery compartment (if reusables) to be sealed against liquid ingress, yet easily opened.
4.3	**Tolerance (to variations, shutdowns)**	NA
4.4	**Protection**	NA
4.5	**Power consumption**	3V lithium battery
4.6	**Other energy supplies**	
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories (mandatory, standard, optional)**	Batteries, light source, blades of various neonatal sizes.
5.2	**Spare parts (main ones)**	Handle
5.3	**Consumables / reagents (open, closed system)**	5 LED should be given as spare
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Operating condition: –Capable of operating continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90% in ideal circumstances. – an ambient air velocity is less than 0.3 m/s. Liquid splash resistant Blades should be autoclavable.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Should be autoclavable
7. STANDARDS AND SAFETY		
7.2	**Certificates (pre-market, sanitary, ..);Performance and safety standards (specific to the device type);Local and/or international**	ISO7376 standard;Manufacturer / supplier should have ISO certificate for quality standard. The lithium battery should comply to IEC 62133 or its equivalent. The device should meet IEC 60601-1, IEC 60601-2 standard requirements. Should be FDA / CE approved product.
8. TRAINING AND INSTALLATION		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	NA

8.2	**Requirements for sign-off**	NA
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided.
	9. WARRANTY AND MAINTENANCE	
9.1	**Warranty**	3 years ; LED upto 6 months
9.2	**Maintenance tasks**	Autoclave
9.3	**Service contract clauses, including prices**	NA
	10. DOCUMENTATION	
10.1	**Operating manuals, service manuals, other manuals**	User, technical and maintenance manuals to be supplied in english language. Certificate of calibration and inspection to be provided. List to be provided of equipment and procedures required for local calibration and routine maintenance. List to be provided of important spares and accessories, with their part numbers and cost. Contact details of manufacturer, supplier and local service agent to be provided.
10.2	**Other accompanying documents**	Service manuals
	11. NOTES	
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/ landline number)**	Any Contract (AMC/MC/add-hoc) to be declared by the manufacturer.
11.2	**Recommendations or warnings**	Any recommendations for best use and supplimentary warning for safety should be declared.

SUCTION PUMP, FOOT OPERATED

Version no. :		1.0
Date:		13/08/13
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Manual emergency suction system
GMDN code		CT2180
Definition		A portable assembly of devices primarily intended to be used by emergency medical services (EMS) to aspirate fluids, secretions, or other foreign materials from a patient's airway by means of suction. It typically consists of a manually-powered (hand or foot-operated) mechanism to drive the suction pump, tubing, a collection container, a vacuum gauge and control knob, and a microbial filter. The pump creates a vacuum in the suction tubing, which is used for the removal of materials into the collection container. This system is typically used during patient transport or for emergency situations.
GENERAL		
1. USE		
1.1	**Clinical purpose**	to aspirate fluids, secretions, or other foreign materials from a patient's airway by means of suction.
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	0-700 mm Hg ± 10 mm regulable, flutter free vacuum control knob, 90 ltrs / min, tight fitting jar cap.
2.2	**Settings**	Manual
2.3	**User's interface**	Manual
2.4	**Software and/or standard of communication(where ever required)**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	Max spec: 32 x 17 x 30 cms
3.2	**Weight (lbs, kg)**	2.5kg
3.3	**Configuration**	NA
3.4	**Noise (in dBA)**	50 dB A ± 3
3.5	**heat dissipation**	NA
3.6	**Mobility, portability**	No
4. ENERGY SOURCE (Electricity, UPS, Solar, Gas, Water, CO_2 ....)		
4.1	**Power Requirements**	NA
4.2	**Battery operated**	NA
4.3	**Tolerance (to variations, shutdowns)**	NA

4.4	**Protection**	NA
4.5	**Power consumption**	NA
4.6	**Other energy supplies**	NA
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories & spare parts**	Autoclavable collection bottles, tapering connector, a vacuum gauge, leak free non-return (NR) valve and control knob.
5.2	**Consumables / reagents (open, closed system)**	10 nos. polypropylene microbial filter (size: 0.45 micrometerparticle size,90% filtration),air inlet: 8mm (outer diameter) 6mm(inner diameter), lubricant for foot paddle, Tubing:8 mm ID x 2 mtr (PVC), polycarbonate jar.
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Operating condition: –Capable of operating continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Complete unit to be easily washable and sterilizable using both alcohol and chlorine agents.
	7. STANDARDS AND SAFETY	
7.1	**Certifications**	Should be FDA / CE approved product, ISO 13485:2003; ISO 10079-2-1999: Medical Suction unit - Part 2 : Manually powered suction equipment.
	8. TRAINING AND INSTALLATION	
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	Safety and operation checks before handover.
8.2	**Requirements for sign-off**	Certificate of Calibration and inspection from the factory.
8.3	**Training of staff (medical, paramedical, technicians) OPTIONAL (Depending upon scope of work order)**	Training of users in operation and basic maintenance shall be provided.
	9. WARRANTY AND MAINTENANCE	
9.1	**Warranty**	3 years
9.2	**Maintenance tasks**	maintainance manual detailing complete maintaining schedule.
9.3	**Service contract clauses, including prices**	Local clinical staff / authorized officer on behalf of purchaser to affirm completion of installation.
	10. DOCUMENTATION	
10.1	**Operating manuals, service manuals, other manuals**	Advanced maintenance tasks required shall be documented User, technical and maintenance manuals to be supplied in english language along with machine diagrams. List to be provided of equipment and procedures required for local calibration and routine maintenance.
10.2	**Other accompanying documents**	List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.
	11. NOTES	
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/ landline number)**	Any Contract (AMC/MC/add-hoc) to be declared by the manufacturer.
11.2	**Recommendations or warnings**	Any recommendations for best use and supplimentary warning for safety should be declared.

SUCTION PUMP PORTABLE

Version no. :		1.0
Date:		13/08/13
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		suction systems
GMDN code(s)		CT1272
Definition		A portable assembly of devices primarily intended to be used by emergency medical services (EMS) to aspirate fluids, secretions, or other foreign materials from a patient's airway by means of suction. It typically consists of a gas-powered mechanism driven by medical air or oxygen (O2) from a gas cylinder to create the suction (e.g., a venturi tube), tubing, a collection container, a vacuum gauge and control knob, and a microbial filter. The pump creates a vacuum in the suction tubing which is used for the removal of materials into the collection container. This system is typically used during patient transport or for emergency situations.
GENERAL		
1	**USE**	
1.1	**Clinical purpose**	to aspirate fluids, secretions, or other foreign materials from a patient's airway by means of suction.
1.2	**Used by clinical department/ward**	All
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	0-700 mm Hg ± 10 regulable, flutter free vacuum control knob, 25ltrs/min, tight fitting jar cap, vacuum capacity; 18 litres/min, maximum depression: -75kPa (-563mmHg).
2.2	**Technical characteristics (continued)**	Wide mouthed 2 x 2 Ltrs. (Polycarbonate) with self sealing bungs and mechanical over flow safety device.
2.3	**Settings**	
2.4	**User's interface**	Manual
2.5	**Software and/or standard of communication(where ever required)**	NA
2.6	**Others**	
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	Max: 43 x 30 x 68 cms
3.2	**Weight (lbs, kg)**	Max: 27Kg
3.3	**Configuration**	
3.4	**Noise (in dBA)**	50 dB A ± 3

3.5	**heat dissipation**	Should maintain upto 36.5 deg temp and the heat disbursed through a exhaust fan.
3.6	**Mobility, portability**	Yes
	4. ENERGY SOURCE (Electricity, UPS, Solar, Gas, Water, CO_2 ....)	
4.1	**Power Requirements**	230 V, 50 Hz, 2 ± 0.5 Amps, 200 watts.
4.2	**Battery operated**	NA
4.3	**Tolerance (to variations, shutdowns)**	Voltage corrector / stabilizer to allow operation at ± 30% of local rated voltage. Use of SMPS to correct voltage.
4.4	**Protection**	Electrical protection by resettable overcurrent breakers or replaceable fuses, fitted in both live and neutral lines.
4.5	**Power consumption**	200W
4.6	**Other energy supplies**	NA
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories (mandatory, standard, optional);Spare parts (main ones)**	autoclavable collection bottles, tapering connector,collection container, a vacuum gauge, lubricant, leak free NR valve and control knob.
5.2	**Consumables / reagents (open, closed system)**	10 nos. polypropelene microbial filter(size: 0.45 micrometer particle size; 90% filtration),Tair inlet: 8mm(outer diameter 6mm (inner diameter), tubing:8 mm ID x 2 mtr (PVC), polycarbonate jar.
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Operating condition: –Capable of operating continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Complete unit to be easily washable and sterilizable using both alcohol and chlorine agents.
	7. STANDARDS AND SAFETY	
7.1	**Certificates (pre-market, sanitary, ..);Performance and safety standards (specific to the device type)**	Should be FDA / CE approved product, ISO 13485:2003; ISO 10079-2-1999: Medical Suction equipment - Part 1 : Electrically owered suction equipment-Safety requirements.
	8. TRAINING AND INSTALLATION	
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	Avalability of 15 amp socket, Supplier to perform installation, safety and operation checks before handover.
8.2	**Requirements for sign-off**	Certificate of Calibration and inspection from the factory.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided.
8.4	**Others**	
	9. WARRANTY AND MAINTENANCE	
9.1	**Warranty**	3 years
9.2	**Maintenance tasks**	maintenance manual detailing complete maintaining schedule.
9.3	**Service contract clauses, including prices**	Local clinical staff to affirm completion of installation.
9.4	**Others**	

10. DOCUMENTATION		
10.1	**Operating manuals, service manuals, other manuals**	Advanced maintenance tasks required shall be documented User, technical and maintenance manuals to be supplied in english language. List to be provided of equipment and procedures required for local calibration and routine maintenance.
10.2	**Other accompanying documents**	List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.
11. NOTES		
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/ landline number)**	Any Contract (AMC/MC/add-hoc) to be declared by the manufacturer.
11.2	**Recommendations or warnings**	Any recommendations for best use and supplimentary warning for safety should be declared.

SYRINGE PUMP

Version no. :		2.0
Date:		13/08/13
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Syringe pump
GMDN code(s)		CT111
Definition		A device designed to precisely drive the plunger of a syringe down its barrel to infuse a solution when it must be administered with a high degree of volume accuracy and rate consistency. Because of the lower flow settings and flow resolution, it is especially appropriate for neonatal, infant, and critical care applications in which small volumes of concentrated drugs are to be delivered over an extended period. It can also be used to administer epidural analgesia.
GENERAL		
1. USE		
1.1	**Clinical purpose**	Designed to precisely drive the plunger of a syringe down its barrel to infuse a solution when it must be administered with a high degree of volume accuracy and rate consistency.
1.2	**Used by clinical department/ward**	Intensive care unit (ICU), radiology department, orthopaedics, emergencies.
1.3	**Overview of functional requirements**	A syringe containing medication is securely mounted on the drive arm. Alarms indicate if any error situations occur. The drive arm infuses the medication at a steady, programmed rate.
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Clinical performances**	Should accept all internationally produced/marketed syringes and should be able to detect it automatically, Should support the Bolus supply of drug on press of single button, as per need and should be able to preset different range of Bolus supply. Preferably the unit should be of Bottom / side loaded to avoid accidental spilling of drugs and damage to the machine.
2.2	**Technical characteristics (specific to this type of device)**	1. Flow rate programmable range at least from 0.1 to 200 ml/hr, in steps of 0.1 ml/hr; and at least from 100 to 1200 ml/hr in steps of 1 ml/hr 2. Saves last infusion rate even when the AC power is switched off 3. Bolus rate should be programmable to approx 500 ml, with infused volume display. 4. Selectable occlusion pressure trigger levels selectable from 300, 500 and 900 mmHg. 5. Must work on commonly available 20, 50 and 100 ml syringes 6. Accuracy of ±2% or better. 7. Maximum pressure generated ≤ 20 psi 8. Automatic detection of syringe size and proper fixing.

		9. Anti-bolus system to reduce pressure on sudden release of occlusion. 10. Pause infusion facility required. 11. Self-check carried out on powering on. 12. Comprehensive alarm package required including: occlusion alarm, near end of infusion pre-alarm and alarm, volume limit pre-alarm and alarm, low battery pre-alarm and alarm, AC power failure, drive disengaged, syringe loading error, maintenance required. 13. Should include KVO (Keep vein open) enabling feature. 14. It should be an open system compliant.
2.3	**Settings**	Single loadable with one syringe of minimum 20ml.
2.4	**User's interface**	Automatic
2.5	**Software and/or standard of communication**	Inbuilt
	3. PHYSICAL CHARACTERISTICS	
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Configuration**	Tamper-resistant case made of impact resistant material Securely mountable on tabletop, IV stand or bed fitting.
3.4	**Noise (in dBA)**	Noise free
3.5	**heat dissipation**	
3.6	**Mobility, portability**	Yes
	4. ENERGY SOURCE (Electricity, UPS, Solar, Gas, Water, CO_2 ....)	
4.1	**Voltage (value, AC or DC, monophase or triphase)**	220 to 240V, 50 Hz
4.2	**Battery operated**	Internal rechargeable battery having at 4 to 6 hours backup for 10ml/hr flow rate with 50ml syringe.
4.3	**Tolerance (to variations, shutdowns)**	10%
4.4	**Protection**	Battery powered alarm for power failure or disconnection.
4.5	**Power consumption**	25W
4.6	**Other energy supplies**	Na
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories (mandatory, standard, optional)**	Clamp for mounting pump on IV stand.
5.2	**Spare parts (main ones)**	
5.3	**Consumables / reagents (open, closed system)**	Battery, syringe holder, PMO lines.
5.4	**Others**	
	BIDDING / PROCUREMENT TERMS / DONATION REQUIREMENTS	
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Operating condition: – Capable of operating continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Capable of cleaning with alcohol or chlorine wipes.

7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type)**	CE or FDA certified; Manufacturer / supplier should have ISO 13485 certificate for quality standard. Electrical safety conforms to standards for electrical safety IEC-60601-1, class II Shall meet IEC 60601-1-2 EMC standard requirements. Certified to IEC-60601-2-24: Particular requirements for the safety of infusion pumps and controllers.
8. TRAINING AND INSTALLATION		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	Supplier to perform installation, safety and operation checks before handover.
8.2	**Requirements for sign-off**	As per requirement.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided.
8.4	**Others**	
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	3 year
9.2	**Maintenance tasks**	Advanced maintenance and calibration tasks required shall be documented.
9.3	**Service contract clauses, including prices**	Local clinical staff to affirm completion of installation.
9.4	**Others**	
10. DOCUMENTATION		
10.1	**Operating manuals, service manuals, other manuals**	User, technical and maintenance manuals to be supplied in english language. List to be provided of equipment and procedures required for local calibration and routine maintenance.
10.2	**Other accompanying documents**	List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.
11. NOTES		
11.1	**Other information**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations or warnings**	

OXYGEN HOOD

Version no. :		1.0
Date:		13/08/13
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Oxygen administration enclosures.
GMDN code(s)		CT 1098
Definition		A device consisting of a rigid/semi-rigid transparent plastic shell that forms an enclosure over an infant's whole body, or the head only, in order to provide an enriched environment of oxygen (O2) to increase the patient's O2 uptake. It is connected to an O2 source and may be used concurrently with increased humidification and temperature control. It is designed to be used for patients adverse to oxygen delivery devices such as a nasal cannula or face mask. This device may include the tubing, a diffuser (to disperse the flow of incoming O2), O2 concentration and humidity sensors. This is a reusable device.
GENERAL		
1	**USE**	
1.1	**Clinical purpose**	to provide an enriched environment of oxygen (O2) to increase the patient's O2 uptake.
1.2	**Used by clinical department/ward**	SNCU/NICU
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	Transparent Polycarbonate unbreakable single molded, Silicon rubber Neck Port adjustment enabled to minimize the wastage of oxygen, Silicon rubber Neck port adjustment to ensures use in Neonate/Infant/Pediatric patients, Oxygen inlet Port.
2.3	**Settings**	N.A.
2.4	**User's interface**	N.A.
2.5	**Software and/or standard of communication(where ever required)**	N.A.
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	small size; medium size
3.2	**Weight (lbs, kg)**	extremely light weight
3.3	**Configuration**	NA
3.4	**Noise (in dBA)**	N.A.
3.5	**heat dissipation**	NA
3.6	**Mobility, portability**	portable
4. ENERGY SOURCE (Electricity, UPS, Solar, Gas, Water, CO_2....)		
4.1	**Power Requirements**	N.A.
4.2	**Battery operated**	N.A.

4.3	**Tolerance (to variations, shutdowns)**	N.A.
4.4	**Protection**	N.A.
4.5	**Power consumption**	N.A.
4.6	**Other energy supplies**	N.A.
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories (mandatory, standard, optional)**	NA
5.2	**Spare parts (main ones)**	NA
5.3	**Consumables / reagents (open, closed system)**	tubing
5.4	**Others**	
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Operating condition: – Capable of operating continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Complete unit to be easily washable and sterilizable using both alcohol and chlorine agents.
	7. STANDARDS AND SAFETY	
7.1	**Certificates (pre-market, sanitary, ..)**	ISO 15001-2010 Should be CE or FDA approved The company should be ISO 13485 certified.
7.2	**Performance and safety standards (specific to the device type)**	NA
	8. TRAINING AND INSTALLATION	
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	NA
8.2	**Requirements for sign-off**	Confirmation in no crack, no leak in hood structure.
8.3	**Training of staff (medical, paramedical, technicians)**	NA
8.4	**Others**	NA
	9. WARRANTY AND MAINTENANCE	
9.1	**Warranty**	1 year
9.2	**Maintenance tasks**	NA
9.3	**Service contract clauses, including prices**	NA
9.4	**Others**	NA
	10. DOCUMENTATION	
10.1	**Operating manuals, service manuals, other manuals**	Advanced maintenance tasks required shall be documented User, technical and maintenance manuals to be supplied in english language. List to be provided of equipment and procedures required for local calibration and routine maintenance
10.2	**Other accompanying documents**	List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.
	11. NOTES	
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/ landline number)**	NA
11.2	**Recommendations or warnings**	NA

OXYGEN CONCENTRATOR

Version no. :		1.0
Date:		13/08/13
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Oxygenators
GMDN code(s)		CT1608
Definition		A portable mains electricity (AC-powered) device designed to concentrate oxygen (O2) from ambient air and deliver the concentrated O2, typically through an attached nasal cannula, to a patient requiring oxygen therapy. It processes the air through an internal filtration system, e.g., a molecular sieve (zeolite granules or membranes), having a large total surface area to separate nitrogen (N2) from the air. It typically consists of an air compressor, filters, dual chambers, a reservoir and controls. The O2 concentration is variable depending on the flow rate utilized. It is used in a home, institution, or a vehicle and typically has internal batteries for transportable use.
GENERAL		
1. USE		
1.1	Clinical purpose	to concentrate oxygen (O2) from ambient air and deliver the concentrated O2, typically through an attached nasal cannula, to a patient requiring oxygen therapy.
1.2	Used by clinical department/ ward	SNCU/NICU
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. flow rate: 0~5 LPM, purity > 93%. 2. O2 delivery pressure: 0.03 to 0.07 Mpa (4.35 - 10.15 PSI). 3. Atomising pellet (ml/min.) > 0.5, uninterupted flow of oxygen. 4. Oxygen monitoring system (optional). 5. Low pressure alarm, high pressure alarm and power failure alarm. 6. Unit capable for supplying oxygen to two outlets simultaneously using two independent flow meters.
2.2	Settings	Should be capable of providing minimum 12 hours of continuous operation.
2.3	User's interface	front panel access to reset switch.
2.4	Software and/or standard of communication (where ever required)	NA
2.5	Others	
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions (metric)	Max spec: 640 mm (H) x 410 mm (W) x 410 mm (D).
3.2	Weight (lbs, kg)	max 30 Kg.
3.3	Configuration	NA

3.4	Noise (in dBA)	<50 db
3.5	heat dissipation	Heat desipated using an internal exhaust, so that a maximum of 36.5 degree C is maintained.
3.6	Mobility, portability	Yes
	4. ENERGY SOURCE (Electricity, UPS, Solar, Gas, Water, CO_2 ....)	
4.1	Power Requirements	230 +/- 10% VAC, 50 Hz, 2 amps
4.2	Battery operated	NA
4.3	Tolerance (to variations, shutdowns)	fuse controlled variation, automatic switch over from AC to DC and vice versa.
4.4	Protection	OVP, earth leakage protection.
4.5	Power consumption	<500 Watts
4.6	Other energy supplies	
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	Accessories (mandatory, standard, optional)	Humidifier Bottles-4nos, power cord- 1no.
5.2	Spare parts (main ones)	
5.3	Consumables / reagents (open, closed system)	Nasal Cannula with extension tubing-2 nos; Gross particle cabinet filter, compressor intake filter and bacterial filter of 0.8-1.0 micron; geolite crystal.
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	Atmosphere / Ambiance (air conditioning, humidity, dust ...)	Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%.Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.
6.2	User's care, Cleaning, Disinfection & Sterility issues	Complete unit to be easily washable and sterilizable using both alcohol and chlorine agents.
	7. STANDARDS AND SAFETY	
7.1	Certificates (pre-market, sanitary, ..);Performance and safety standards (specific to the device type)	CE or FDA approved and company should be ISO 13485 certified; and shall meet IEC 60601-1, IEC 60601-1-2 standard requirements; and compile with ISO 15001-2010
	8. TRAINING AND INSTALLATION	
8.1	Pre-installation requirements: nature, values, quality, tolerance	Availability of 5 amp/15 Amp. Electrical socket (2 nos) for each warmer.
8.2	Requirements for sign-off	Certificate of Calibration and inspection from the factory.
8.3	Training of staff (medical, paramedical, technicians)	user training manual required.
8.4	Others	List of important spare parts and accessories with their part number and costing.
	9. WARRANTY AND MAINTENANCE	
9.1	Warranty	3 years
9.2	Maintenance tasks	maintainance manual detailing complete maintaining schedule.
9.3	Service contract clauses, including prices	warranty of one year with free servicing (min. 3) during warranty.
9.4	Others	The spare price list of all spares and accessories (including minor) required for maintenance and repairs in future after guarantee / warranty period should be attached.
	10. DOCUMENTATION	
10.1	Operating manuals, service manuals, other manuals	Yes

10.2	Other accompanying documents	To be supplied
10.3	Recommendations for maintenance	User/Technical/Maintenance manuals to be supplied in English.
10.4	Others	
	11. NOTES	
11.1	Service Support Contact details (Hierchy Wise; including a toll free/landline number)	Any Contract (AMC/MC/add-hoc) to be declared by the manufacturer.
11.2	Recommendations or warnings	Any recommendations for best use and supplimentary warning for safety should be declared.

WEIGHING SCALE

Version no. :		1.0
Date:		13/08/13
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		NA (Instrument)
GMDN code(s)		NA
Definition		NA
GENERAL		
1. USE		
1.1	**Clinical purpose**	to measure body mass of the neonate
1.2	**Used by clinical department/ ward**	NICU/SNCU
1.3	**Overview of functional requirements**	
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. Table top, light and portable. 2. Built in rechargeable battery. 3. Easy to clean baby tray (acrylic). 4. Zero weight adjustment facility. 5. Quick, clear digital read outs. 6. Measurement does not change with position of baby on the pan. 7. Provision to measure the height of the baby in its laying position. 8. Accuracy: 5g, resolution: 1g, limit: 10gm ~ 15kg.
2.2	**Settings**	Auto setting to 0.00 once a the machine is switched on or when no external weight has been put on.
2.3	**User's interface**	LCD display.
2.4	**Software and/or standard of communication(where ever required)**	in built
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	Base: 300mm x 265mm x 85mm, Pan: 510mm x 300mm x 85mm.
3.2	**Weight (lbs, kg)**	NA
3.3	**Configuration**	N.A.
3.4	**Noise (in dBA)**	N.A.
3.5	**heat dissipation**	NA
3.6	**Mobility, portability**	portable

4. ENERGY SOURCE (Electricity, UPS, Solar, Gas, Water, CO_2 ....)		
4.1	**Power Requirements**	230 V AC,
4.2	**Battery operated**	6V, one hour backup
4.3	**Tolerance (to variations, shutdowns)**	NA
4.4	**Protection**	NA
4.5	**Power consumption**	NA
4.6	**Other energy supplies**	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories (mandatory, standard, optional)**	NA
5.2	**Spare parts (main ones)**	NA
5.3	**Consumables / reagents (open, closed system)**	NA
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Operating condition: – Capable of operating continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90% in ideal circumstances. – an ambient air velocity less than 0.3 m/s.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Complete unit to be easily washed and disinfected using both alcohol and chlorine agents.
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type); Local and/or international**	The Scale should be as per BIS specifications. The scale should have ISI mark ie IS: 2489 Or CE/FDA certified. Should have model approval from Legal Metrology Dept., Govt. of India.
8. TRAINING AND INSTALLATION		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	NA
8.2	**Requirements for sign-off**	NA
8.3	**Training of staff (medical, paramedical, technicians)**	NA
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	one year
9.2	**Maintenance tasks**	calliberation schedule to be provided.
9.3	**Service contract clauses, including prices**	Any Contract (AMC/MC/add-hoc) to be declared by the manufacturer.
10. DOCUMENTATION		
10.1	**Operating manuals, service manuals, other manuals**	NA
10.2	**Other accompanying documents**	NA
10.3	**Recommendations for maintenance**	Cautionary Note: Do not press the weighing pan with your hand. It could damage the load cell system in the weighing machine.
10.4	**Others**	
11. NOTES		
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/landline number)**	Any Contract (AMC/MC/add-hoc) to be declared by the manufacturer.
11.2	**Recommendations or warnings**	Any Contract (AMC/MC/add-hoc) to be declared by the manufacturer.

PULSE OXYMETER, LINE POWERED

Version no. :		2.0
Date:		13/08/13
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Pulse oximeter
GMDN code(s)		CT 1446
Defination		A mains electricity (AC-powered) photoelectric device intended for the continuous measurement and display of haemoglobin oxygen saturation (SpO2). The signals, typically produced by light-emitting diodes (LEDs) and a receiving detector in a probe, or directly built-in, are used to make the measurements using the principle of spectrophotometry. The oximeter displays the SpO2 values and may calculate / display other parameters, e.g., pulse rate. The device is typically used at the bedside.
GENERAL		
1. USE		
1.1	**Clinical purpose**	measurement and display of haemoglobin oxygen saturation (SpO2).
1.2	**Used by clinical department/ ward**	All
1.3	**Overview of functional requirements**	Continuously displays patient oxygen saturation in real time using an external probe on the skin Contains adjustable alarms to alert when either saturation or heart rate is low Reusable, sterilisable probes are robust and easily connected and disconnected Operates from mains voltage or from internal rechargeable battery.
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	a) SpO2 measurement range at least 40-70 and 70 to 99 %, minimum gradation 1%. b) Accuracy of SpO2 better than ± 1% for range 40-70 and better than ± 3% for range 70-99. c) Pulse rate range at least 30 to 240 bpm, minimum gradation 1 bpm. d) Accuracy of pulse rate better than ± 5 bpm. e) Signal strength or quality to be visually displayed. f) Audiovisual alarms required: high and low SpO2 and pulse rate (operator variable settings), sensor disconnected, sensor failure, low battery. g) TFT Screen h) plethysmograph (may be in form of bar) display is mandatory.
2.2	**Settings**	Shoud have minimum 24 hrs trend memory for SpO2 & PR.
2.3	**User's interface**	Easily accessible touch button to operate the machine.

2.4	**Software and/or standard of communication**	in built
	3. PHYSICAL CHARACTERISTICS	
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	should be less than 5 kg.
3.3	**Configuration**	Case is to be hard and splash proof. Display must allow easy viewing in all ambient light levels. Supplied in protective case for clean storage and safe transport.
3.4	**Noise (in dBA)**	<50dBA
3.5	**heat dissipation**	dispersed through exhaust
3.6	**Mobility, portability**	mobile
	4. ENERGY SOURCE (Electricity, UPS, Solar, Gas, Water, CO_2 ....)	
4.1	**Voltage (value, AC or DC, monophase or triphase)**	220 to 240V, 50 Hz
4.2	**Battery operated**	Internal, replaceable, rechargeable battery allows operation for at least four hours in the event of power failure Battery charger to be integral to mains power supply, and to charge battery during mains power operation of unit.
4.3	**Tolerance (to variations, shutdowns)**	Voltage corrector / stabilizer / UPS to allow operation at ± 30% of local rated voltage.
4.4	**Protection**	Electrical protection by resettable circuit breakers in both live and neutral supply lines, Alarms should include Power failure.
4.5	**Power consumption**	50-100 W
4.6	**Other energy supplies**	Mains supply cable to be at least 3m in length.
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories (mandatory, standard, optional)**	Two reusable probes each for adult, paediatric and infant use, Y Probes with clips for infant use and Forehead SpO2 sensors for detection of low saturation levels (less than 70%)/ flex probe with provision of fixation.
5.2	**Spare parts (main ones)**	Two sets of spare fuses (if non-resettable fuses used).
5.3	**Consumables / reagents (open, closed system)**	NA
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Operating condition: – Capable of operating continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	cleanable with alcohol or chlorine wipes.
7	**STANDARDS AND SAFETY**	
7.1	**Certificates (pre-market, sanitary, ..), Performance and safety standards (specific to the device type);Local and/or international**	Should be FDA / CE approved product ISO 80601-2-61-2011: Medical Electrical equipment- part 2-61: Particular requirements for the basic safety snd essential performance of pulse oxymeter. Electrical safety conforms to standards for electrical safety IEC-60601-1, EMC safety confirms to IEC 60601-1-2 standard requirement. Manufacturer / supplier should have ISO 13485 certificate for quality standard.
	8. TRAINING AND INSTALLATION	
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	Electrical sockets
8.2	**Requirements for sign-off**	Supplier to perform installation, safety and operation checks before handover Local clinical staff to affirm completion of installation.

8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided. Advanced maintenance tasks required shall be documented.
8.4	**Others**	
	9. WARRANTY AND MAINTENANCE	
9.1	**Warranty**	3 years
9.2	**Maintenance tasks**	maintenance manual detailing complete maintaining schedule.
9.3	**Service contract clauses, including prices**	warranty of three year with free servicing (min. 3) during warranty.
9.4	**Others**	The spare price list of all spares and accessories (including minor) required for maintenance and repairs in future after guarantee / warranty period should be attached.
	10. DOCUMENTATION	
10.1	**Operating manuals, service manuals, other manuals**	User and maintenance manuals to be supplied in English language. Certificate of calibration and inspection to be provided. List to be provided of equipment and procedures required for local calibration and routine maintenance List to be provided of important spares and accessories, with their part numbers and cost. Contact details of manufacturer, supplier and local service agent to be provided.
10.2	**Other accompanying documents**	User/Technical/Maintenance manuals to be supplied in English.
	11. NOTES	
11.1	**Other information**	Any Contract (AMC/MC/add-hoc) to be declared by the manufacturer.
11.2	**Recommendations or warnings**	Any recommendations for best use and supplimentary warning for safety should be declared.

EXAMINATION TREATMENT LIGHT

Version no. :		2.0
Date:		13/08/13
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Examination/treatment light
GMDN code(s)		CT 1268
Definition		A device that provides light to illuminate the site of examination and/or treatment of the patient. It typically consists of one or more light bulb(s), which reflect the light via reflectors or mirrors depending upon the construction and will often be mounted on a pantograph counterbalance assembly that is attached to the mobile mount. It is usually used during examination or treatment in locations that do not have the required lighting installed. This device is designed to be easily moved from one location to another.
GENERAL		
1. USE		
1.1	**Clinical purpose**	Provides light to illuminate the site of examination and/or treatment of the patient
1.2	**Used by clinical department/ ward**	All
1.3	**Overview of functional requirements**	Provides clear and cool light to operating area Minimizes shadows and distortion of colour Mounted on mobile base Single head must be easily moved by operator to direct light to required area Integral rechargeable battery for operation without mains electricity
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. Colour temperature to be between 3,000 and 5,000 K; shadowless. 2. Maximum illumination level at 1m distance to be at least 60,000 lux. 3. Colour rendering index to be 93 or greater. 4. Minimum bulb life required 1,000 hours (incandescent type) or 20,000 hrs (LED type). 5. Field diameter required ||16cm, field depth required || 50cm. 6. Focal length required || 65 cm. 7. Heat to light ratio to be ≤ 6 mW/m2.lx. 8. Brightness control to allow full adjustment from zero to maximum illumination. 9. Bulb voltage and type to be clearly labeled on external body. 10. Replacement bulbs to be locally available. 11. Front panel to include power switch and battery state indicator. 12. Automatic switching to battery power in the event of power failure.

2.2	**Settings**	Manual
2.3	**User's interface**	Manual
2.4	**Software and/or standard of communication**	NA
	3. PHYSICAL CHARACTERISTICS	
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	less than 30 kgs
3.3	**Configuration**	Case is to be hard, splashproof and corrosion resistant. Movement must be easily achieved by operator of height 1.5 m Light head mounting to allow vertical and rotational movement, capable of illuminating at least 1 m high table Handle for movement must be easy to grasp and clean Light must remain steady on position and balanced once moved. Base to have at least four fully 360 degree swivel castors, minimum diameter 75mm Whole system to be stable for all positions of light head. All power supply and battery location to be within access for ease in replacement.
3.4	**Noise (in dBA)**	NA
3.5	**heat dissipation**	Should maintain cool temp and the heat disbursed through a exhaust fan.
3.6	**Mobility, portability**	Portable on castors.
	4. ENERGY SOURCE (Electricity, UPS, Solar, Gas, Water, CO_2 ....)	
4.1	**Voltage (value, AC or DC, monophase or triphase)**	220 to 240V, 50 Hz
4.2	**Battery operated**	Internal, replaceable, rechargeable battery allows operation for at least eight hours in the event of power failure. Battery charger to be integral to mains power supply, and to charge battery during mains power operation of unit.
4.3	**Tolerance (to variations, shutdowns)**	Voltage corrector / stabilizer to allow operation at ± 30% of local rated voltage.
4.4	**Protection**	Electrical protection by resettable overcurrent breakers or replaceable fuses, fitted in both live and neutral lines.
4.5	**Power consumption**	100 W or below
4.6	**Other energy supplies**	Mains cable to be at least 3m length
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories (mandatory, standard, optional)**	NA
5.2	**Spare parts (main ones)**	NA
5.3	**Consumables / reagents (open, closed system)**	Two sets of spare fuses (if replaceable fuses used). Ten sets of replacement bulbs (if incandescent).
5.4	**Others**	NA
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Operating condition: – Capable of operating continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Unit layout to enable easy cleaning and sterilization of all surfaces.
	7. STANDARDS AND SAFETY	
7.1	**Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type); Local and/or international**	Should be FDA / CE approved product Manufacturer / supplier should have ISO 13485 certificate for quality standard. Electrical safety conforms to standards for electrical safety IEC-60601-1 Shall meet IEC-60601-1-2 (General requirements for safety - electromagnetic compatibility).

8. TRAINING AND INSTALLATION		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	NA
8.2	**Requirements for sign-off**	Supplier to perform installation, safety and operation checks before handover Local clinical staff to affirm completion of installation.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided Advanced maintenance tasks required shall be documented.
8.4	**Others**	
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	One year;
9.2	**Maintenance tasks**	NA
9.3	**Service contract clauses, including prices**	NA
9.4	**Others**	NA
10. DOCUMENTATION		
10.1	**Operating manuals, service manuals, other manuals**	User, technical and maintenance manuals to be supplied in English language. Certificate of calibration and inspection to be provided. List to be provided of equipment and procedures required for local calibration and routine maintenance List to be provided of important spares and accessories, with their part numbers and cost. Contact details of manufacturer, supplier and local service agent to be provided.
11. NOTES		
11.1	**Other information**	Any Contract (AMC/MC/add-hoc) to be declared by the manufacturer.
11.2	**Recommendations or warnings**	Any recommendations for best use and supplimentary warning for safety should be declared.

MONITOR, VITAL SIGNS

Version no. :		1.0
Date:		13/08/13
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Patient Monitors/Monitoring Systems.
GMDN code(s)		CT1444
Definition		A device assembly designed to continuously measure and display multiple vital physiological parameters of newborn and premature infants, especially those under critical care. It is typically capable of monitoring parameters such as electrocardiogram (ECG), respiration rate, heart rate, blood pressure, and body temperature; it may also assess haemoglobin oxygen saturation (SpO2) through transcutaneous sensors that measure both transcutaneous oxygen (tcpO2) and transcutaneous carbon dioxide ($tcpCO_2$) saturation. The system typically includes sensors with appropriate size and design for infant use.
GENERAL		
1. USE		
1.1	**Clinical purpose**	Designed to continuously measure and display multiple vital physiological parameters of newborn and premature infants, especially those under critical care.
1.2	**Used by clinical department/ ward**	All
1.3	**Overview of functional requirements**	Operates from mains voltage or from internal rechargeable battery.Operator can set audio visual alarm levels for low or high levels of each parameter independently.Allows display of single, 3 lead ECG or simultaneous display of at least 5 waves ECG selected from up to 12 points.Display to be digital of all active parameters and trace display for at least three selectable parameters. Continuous display on screen of neonatal or infant ECG, respiration and heart rates,non-invasive blood pressure, body temperature and SpO2.
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. ECG patient connectors that are sterilisable and reusable are acceptable though reusable cables that attach to disposable connection patches are preferred. 2. Multichannel (up to 12 leads) ECG measurement and selectable display of upto 5 leads at a time. 3. Temperature probe to be reusable, external skin contact type. Temperature range at least 30 to 40 deg C, minimum gradation 0.1 deg C. 4. Heart rate measurement range to be at least 30 to 250 bpm, with accuracy better than ± 5 bpm and minimum gradation 1 bpm. 5. SpO2 measurement range at least 40-70 % and 70 to 99 %, with accuracy better than ± 1% for 40-70 range and better than ± 3% for 70-99 range and minimum gradation 1%. 6. Blood pressure monitoring range at least 30 to 300 mmHg, minimum gradation 1 mmHg.

		7. Respiration rate measurement range at least 0 to 100 bpm, minimum gradation 1 bpm. 8. Trend display of each parameter over at least previous 24 hours to be selectable. 9. TFT screen.
2.2	**Settings**	User operated 1mV ECG test marker function required.
2.3	**User's interface**	Manual (touch screen or remote operated not mandatory).
2.4	**Software and/or standard of communication**	Audio Visual alarms required: high and low levels for each parameter (operator variable settings), sensor / wire / probe disconnected, low battery.
	3. PHYSICAL CHARACTERISTICS	
3.1	**Dimensions (metric)**	Screen size minimum: 8"X6".
3.2	**Weight (lbs, kg)**	5 kgs-7 kgs.
3.3	**Configuration**	Case is to be hard and splash proof. Display must allow easy viewing in all ambient light levels.Cable connectors to be designed so as fit correct socket only.
3.4	**Noise (in dBA)**	<50 dB.
3.5	**heat dissipation**	Heat Dissipiation: Should maitain nominal Temp and the heat should be disbursed through a exhaust cooling fan.
3.6	**Mobility, portability**	Supplied in protective case for clean storage and safe transport.
	4. ENERGY SOURCE (Electricity, UPS, Solar, Gas, Water, CO_2....)	
4.1	**Voltage (value, AC or DC, monophase or triphase)**	220 to 240V, 50 Hz
4.2	**Battery operated**	Battery charger to be integral to mains power supply, and to charge battery during mains power operation of unit.Battery powered, silenceable alarm for power failure.Internal, replaceable, rechargeable battery allows operation for at least one hour in the event of power failure.
4.3	**Tolerance (to variations, shutdowns)**	Voltage corrector / stabilizer to allow operation at ± 30% of local rated voltage.
4.4	**Protection**	Electrical protection provided by fuses in both live and neutral supply lines.
4.5	**Power consumption**	
4.6	**Other energy supplies**	Mains cable to be at least 3m length.
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories & Spare Parts**	2 pairs, 12 lead ECG cable. 5 sets of ECG connection electrodes (if reusable type) of ECG connection electrodes (if disposable type). 5 lead ECG cable.Two reusable SpO2 probes for infant use. Two reusable neonatal cuffs.Two external skin temperature probes.Two sets of spare fuses (if non-resettable fuses used).
5.2	**Consumables / reagents (open, closed system)**	5 tubes electrode gel (if required).
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Operating condition: – Capable of operating continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	The case is to be cleanable with alcohol or chlorine wipes.
	7. STANDARDS AND SAFETY	
7.1	**Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type); Local and/or international**	Should be FDA / CE approved product. Electrical safety conforms to standards for electrical safety IEC-60601-1. Shall meet IEC-60601-1-2 (General requirements for safety - electromagnetic compatibility).Also conforms to IEC 60601-2-27 (Particular requirements for the safety of electrocardiographic monitoring equipment). Manufacturer / supplier should have ISO certificate for quality standard. Shall meet IEC 60601-2-49 multi function patient monitoring equipment standard requirement.

8. TRAINING AND INSTALLATION		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	Supplier to perform installation, safety and operation checks before handover.
8.2	**Requirements for sign-off**	Clear and complete disply of all functions.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	3 years
9.2	**Maintenance tasks**	maintainance manual detailing complete maintaining schedule.
9.3	**Service contract clauses, including prices**	warranty of 3 years with free servicing (min. 3/year) during warranty.
9.4	**Others**	The spare price list of all spares and accessories (including minor) required for maintenance and repairs in future after guarantee / warranty period should be attached
10. DOCUMENTATION		
10.1	**Operating manuals, service manuals, other manuals**	Advanced maintenance tasks required shall be documented User, technical and maintenance manuals to be supplied in English language. List to be provided of equipment and procedures required for local calibration and routine maintenance.
10.2	**Other accompanying documents**	List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.
11. NOTES		
11.1	**Other information**	Any Contract (AMC/MC/add-hoc) to be declared by the manufacturer.
11.2	**Recommendations or warnings**	Any recommendations for best use and supplimentary warning for safety should be declared.

ECG UNIT

Version no. :		1.0
Date:		13/08/13
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Multichannel Electrocardiographic
GMDN code(s)		CT 1115
Definition		A mains electricity (AC-powered) bedside device designed to continuously detect, measure, and display a patient's electrocardiogram (ECG) through leads and sensors attached to the patient; it also typically displays heart rate. The device is typically equipped with audible and/or visual alarms that are triggered when the patient's parameters drop below or exceed pre-set limits.
GENERAL		
1. USE		
1.1	**Clinical purpose**	Continuously detect, measure, and display a patient's electrocardiogram (ECG) through leads and sensors attached to the patient
1.2	**Used by clinical department/ ward**	All
1.3	**Overview of functional requirements**	Continuous display of patient ECG and heart rate on screen Allows display of single, 5 lead ECG or simultaneous display of at least 5 waves selected from up to 12 points Operator can set audiovisual alarm levels for low or high heart rate Operates from mains voltage or from internal rechargeable battery Patient connectors that are sterilisable and reusable are preferred, though reusable cables that attach to disposable connection patches are also acceptable Hard copy printout of traces will be required
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. Heart rate measurement range to be at least 30 to 250 bpm, with accuracy better than ± 5 bpm. 2. Heart rate trend display of at least previous 24 hours. 3. Arrhythmia detection facility required; minimum gradation of 1 bpm. 4. Heart rate measurement range to be at least 30 to 250 bpm, with accuracy better than ± 5 bpm.
2.2	**Settings**	Audiovisual alarms required: high and low heart rate (operator variable settings), cardiac arrhythmia, sensor / wire disconnected, low battery.
2.3	**User's interface**	Manual
2.4	**Software and/or standard of communication**	In built
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	NA

3.2	**Weight (lbs, kg)**	less than 5 Kgs
3.3	**Configuration**	Case is to be hard and splash proof Display must allow easy viewing in all ambient light levels Supplied in protective case for clean storage and safe transport.
3.4	**Noise (in dBA)**	<50 dB
3.5	**heat dissipation**	Heat Dissipiation: Should maitain nominal Temp and the heat should be disbursed through a exhaust cooling fan.
3.6	**Mobility, portability**	Supplied in protective case for clean storage and safe transport.
	4. ENERGY SOURCE (Electricity, UPS, Solar, Gas, Water, CO_2 ....)	
4.1	**Voltage (value, AC or DC, monophase or triphase)**	220 to 240V, 50 Hz
4.2	**Battery operated**	Battery powered, silenceable alarm for power failure Battery charger to be integral to mains power supply, and to charge battery during mains power operation of unit Internal, replaceable, rechargeable battery allows operation for at least one hour in the event of power failure.
4.3	**Tolerance (to variations, shutdowns)**	Voltage corrector / stabilizer to allow operation at ± 30% of local rated voltage.
4.4	**Protection**	Electrical protection provided by fuses in both live and neutral supply lines.
4.5	**Power consumption**	
4.6	**Other energy supplies**	Mains cable to be at least 3m length.
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories (mandatory, standard, optional)**	12 lead ECG cable. 5 lead ECG cable (if option offered). 100 sets of ECG connection electrodes (if disposable type). 5 sets of ECG connection electrodes (if reusable type).
5.2	**Spare parts (main ones)**	Two sets of spare fuses (if non-resettable fuses used).
5.3	**Consumables/reagents (open, closed system)**	5 tubes electrode gel (if required).
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Operating condition: – Capable of operating continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	The case is to be cleanable with alcohol or chlorine wipes
	7. STANDARDS AND SAFETY	
7.1	**Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type); Local and/or international**	Should be FDA / CE approved product; Manufacturer / supplier should have ISO 13485 certificate for quality standard. Electrical safety conforms to standards for electrical safety IEC-60601-1 Shall meet IEC-60601-1-2 (General requirements for safety - electromagnetic compatibility) and IEC 60601-2-25 (essential performance of electrocardiographs)
	8. TRAINING AND INSTALLATION	
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	Availability of 5 amp/15 Amp. Electrical socket
8.2	**Requirements for sign-off**	Supplier to perform installation, safety and operation checks before handoverLocal clinical staff to affirm completion of installation
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided Advanced maintenance tasks required shall be documented

9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	3 year
9.2	**Maintenance tasks**	maintainance manual detailing complete maintaining schedule.
9.3	**Service contract clauses, including prices**	warranty of one year with free servicing (min. 3) during warranty.
9.4	**Others**	The spare price list of all spares and accessories (including minor) required for maintenance and repairs in future after guarantee / warranty period should be attached.
10. DOCUMENTATION		
10.1	**Operating manuals, service manuals, other manuals**	User, technical and maintenance manuals to be supplied in english language. Certificate of calibration and inspection to be provided. List to be provided of equipment and procedures required for local calibration and routine maintenance List to be provided of important spares and accessories, with their part numbers and cost. Contact details of manufacturer, supplier and local service agent to be provided.
10.2	**Other accompanying documents**	User/Technical/Maintenance manuals to be supplied in English.
11. NOTES		
11.1	**Other information**	Any Contract (AMC/MC/add-hoc) to be declared by the manufacturer.
11.2	**Recommendations or warnings**	Any recommendations for best use and supplimentary warning for safety should be declared.

X-RAY, MOBILE

Version no. :		1.0
Date:		13/08/13
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		basic diagnostic x-ray system
GMDN code(s)		CT 692
Definition		An assembly of devices that comprise an analogue general-purpose mobile diagnostic x-ray system used in a variety of routine x-ray imaging applications. It is typically an x-ray film based system using analogue or analogue-to-digital techniques for image capture and display. The mobile design allows it to operate on-line or by battery and to be driven or pushed by an operator to various locations within a building. It is commonly used for bedside imaging and for interventional and intraoperative imaging.
GENERAL		
1. USE		
1.1	**Clinical purpose**	General-purpose mobile diagnostic x-ray system used in a variety of routine x-ray imaging applications.
1.2	**Used by clinical department/ ward**	Radiology services
1.3	**Overview of functional requirements**	Provides X-ray film images of all parts of the body. X ray generator and cassette holder can be moved to image required body part. DICOM compatible image storage and transfer required. Last image hold facility required, displayed on clear, movable screen.
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. Must have a digital display of mAs and kV, and an electronic timer. 2. kV range at least 40kV to 125kV, digitally displayed mAs range at least 0.5 to 200 mAs or more. 3. Exposure time range at least 1 ms to 5 s. 4. Automatic exposure control facility required. 5. Tube power rating at least 20 kW. 6. Must have a rotating anode with focal spot size less than 1mm. 7. Heat storage capacity of the anode at least 200,000 HU. 8. Adjustable multileaf collimator, rotatable ±90 deg with patient centering light. 9. Alphanumeric annotation of images required. 10. Must be supplied with protective dust cover at least for control panel.

2.2	**Settings**	The system should be capable of storing at least 3000 images, with capacity for removable media storage. Image to be displayed immediately after exposure.
2.3	**User's interface**	Image display to be contrast- and brightness- adjustable, at least 18 inches diagonal size. Exposures by remote control should also be possible, with operating distance > 10 m. The exposure release switch should be detachable, with a cord of at least 5 metres long.
2.4	**Software and/or standard of communication**	in built
	3. PHYSICAL CHARACTERISTICS	
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Configuration**	The unit must have an effective braking system for parking, transport and emergency braking. The tube stand must be fully counterbalanced for rotation in all directions. It must have an articulated arm for imaging with any patient position. All cables should be concealed in the arm system.
3.4	**Noise (in Dba)**	<60dB
3.5	**heat dissipation**	Should maintain normal temp and the heat disbursed through a exhaust fan.
3.6	**Mobility, portability**	When motor or battery is non-functional, free movement by pushing must be possible. Motorized movement capable of ascending slope of up to 7 deg from horizontal. Unit base wheels must be easily accessible for cleaning. Whole unit moved by battery powered motor or pushed by operator to required department.
	4. ENERGY SOURCE (Electricity, UPS, Solar, Gas, Water, CO2 ....)	
4.1	**Voltage (value, AC or DC, monophase or triphase)**	220 to 240V, 50 Hz
4.2	**Battery operated**	NA
4.3	**Tolerance (to variations, shutdowns)**	Resettable overcurrent breaker to be fitted on both live and neutral supply lines.
4.4	**Protection**	Low battery' indicator required.
4.5	**Power consumption**	Voltage corrector / stabilizer to allow operation at ± 30% of local rated voltage.
4.6	**Other energy supplies**	NA
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories (mandatory, standard, optional)**	To be supplied with adult size protective lead apron and mobile protective barrier.
5.2	**Spare parts (main ones)**	control cable, tranformer, exposure switch.
5.3	**Consumables / reagents (open, closed system)**	X-ay films delat in different tendor.
5.4	**Others**	Portable radiation hazard warning signs to be supplied with unit.
	6 ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Operating condition: – Capable of operating continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90% in ideal circumstances..\
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	The case is to be cleanable with alcohol or chlorine wipes

	7. STANDARDS AND SAFETY	
7.1	**Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type); Local and/or international**	Should be FDA, CE or UL approved product. Electrical safety conforms to standards for electrical safety IEC-60601, Class I Radiation safety to be certified to IAEA standards and AERB type approval (national standards). Shall meet IEC 60601-1-3 standard requirement. Manufacturer / supplier should have ISO certificate for quality standard.
	8. TRAINING AND INSTALLATION	
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	Dosemeter should be available with the operator; lead gown to be supplier for the operator.
8.2	**Requirements for sign-off**	Supplier to perform installation, safety and operation checks before handover Local clinical staff to affirm completion of installation.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided.
8.4	**Others**	Advanced maintenance tasks required shall be documented.
	9. WARRANTY AND MAINTENANCE	
9.1	**Warranty**	3 years
9.2	**Maintenance tasks**	maintainance manual detailing complete maintaining schedule.
9.3	**Service contract clauses, including prices**	warranty of 3 year with free servicing (min. 3/year) during warranty.
9.4	**Others**	The spare price list of all spares and accessories (including minor) required for maintenance and repairs in future after guarantee / warranty period should be attached.
	10. DOCUMENTATION	
10.1	**Operating manuals, service manuals, other manuals**	User, technical and maintenance manuals to be supplied in english language.
10.2	**Other accompanying documents**	Certificate of calibration and inspection to be provided. List to be provided of important spares and accessories, with their part numbers and cost.
10.3	**Recommendations for maintenance**	List to be provided of equipment and procedures required for local calibration and routine maintenance.
10.4	**Others**	Contact details of manufacturer, supplier and local service agent to be provided.
	11. NOTES	
11.1	**Other information**	Any Contract (AMC/MC/add-hoc) to be declared by the manufacturer.
11.2	**Recommendations or warnings**	Any recommendations for best use and supplimentary warning for safety should be declared.

TRANSPORT INCUBATOR

Version no. :		1.0
Date:		13/08/13
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		infant incubator
GMDN code(s)		CT1482
Definition		An electrically-powered unit designed to provide an enclosed controlled environment to maintain appropriate temperature and humidity levels mainly for premature infants and other newborns who cannot effectively regulate their body temperature; it is typically on wheels and also designed for transporting infants either outside or within the healthcare facility. It typically consists of a clear removable plastic hood with a mattress and operates using mains electricity (AC-powered) when not in use for transportation. During transport, it is connected to an ambulance electrical outlet or is battery-powered from a battery pack.
GENERAL		
1. USE		
1.1	**Clinical purpose**	designed to provide an enclosed controlled environment to maintain appropriate temperature and humidity levels mainly for premature infants and other newborns who cannot effectively regulate their body temperature
1.2	**Used by clinical department/ ward**	(Ex : Intensive care unit (ICU), radiology department, orthopaedics, emergencies, ...)
1.3	**Overview of functional requirements**	Control of air temperature and infant skin temperature. Clear, hard cabinet for infant viewing Easy access control panel, with light touch operation switches. Facility to elevate base, adjustable range. Self-test functions are performed. Built for transport of infants between wards or health facilities, including by vehicle Must have skin temperature display
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. Visual and audible alarms for: (i) Patient and air high/low temperature alarm. (ii) Air circulation / probe / system / power failure alarm. 2. Heater power indicator. 3. Air velocity 0.35m/sec. 4. Oxygen input flow rate 5 to15 litres/min or oxygen concentration range 25 to 70%. 5. Maximum CO2 concentration inside incubator 0.2%. 6. Internal noise level < 60 dB. 7. Mode of operation should be properly displayed. 8. Green indicator light shlould be provided for its ready to be in normal use. 9. Infants straps should be provided to restrict the baby movement.

		10. skin temperature probe should be small in size not more than 10mm diameter and 4mm in height to fix the probe firmly on the infant. Baby contact material should be biocompatible as per ISO 10993 standard requirement. 11. Infant bed should be drawable. Mattress foam density should be minimum 25kg./cm3 and infant bed mattress cover should be biocompatible material. 12. Examination light should be provided for inspection. 13. Should have heater power indicator. 14. Warmup time 30-40 minutes and shall not differ by more than 20%. 15. Shall be equipped with a thermal cut-out. It shall be so arranged that the heater is disconnected and an auditory and visual warning is given at an incubator temperature which does not exceed 40 deg C. 16. Should have elbow operateable ports and head access door. 17. It should not topple over at 10 deg inclined plane. 18. Patient skin temperature range: 35 deg C to 37.5 deg C. over ride upto 39 deg C. 19. Air temperature range: 30 deg C to 39 deg C; Temperature resolution ± 0.1 deg C; Temperature accuracy less than ± 0.2 deg C.
2.2	**Settings**	Patient skin temperature range: 35 deg C to 37.5 deg C. over ride upto 39 deg C Air temperature range: 30 deg C to 39 deg C. humidity: 40-80%.
2.3	**User's interface**	Display is to be backlit and allows easy viewing in all ambient light levels.
2.4	**Software and/or standard of communication**	In built
2.5	**Others**	1. Patient leakage current should be less than 100 µA. 2. Temperature on the baby mattress should not exceed 40 deg C and 43 deg for other materials. 3. Uniformity of temperature on the horizontal mattress shall not exceed 1.5 deg C and in tilted mattress not exceed 2 deg C. 4. The overshoot temperature shall not exceed 2 deg C. 5. The stability of temperature during steady temperature shall not differ from the average temperature by more than 1 deg C.
	3. PHYSICAL CHARACTERISTICS	
3.1	**Dimensions (metric)**	Baby bed should be atleast 60X30cm and the canopy should be atleast 80X40 cm.
3.2	**Weight (lbs, kg)**	not exceeding 40kg. (without cylinders).
3.3	**Configuration**	Oxygen port with tubing, also mount for oxygen cylinder of 5 litre size. Accommodates shelves, suction unit and I/V poles. Double-walled cabinet with at least two hand ports. Should have colapsible trolley with lockable castors. Mounted on mobile base, lowest height setting of which is at least 80 cm high Minimum castor diameter 12cm At least two castors must be fitted with brake facility Castors must be made of conductive material and rotate (swivel) freely around the vertical axis The canopy and infant bed should be crevice free for ease of cleaning.
3.4	**Noise (in dBA)**	<60dBA; Audible sound level should be atleast 65dBA at 3meter distance from the device; the alarm sound level in the compartment shall not exceed dBA.
3.5	**heat dissipation**	Should maintain upto 37 deg temp.
3.6	**Mobility, portability**	Yes, on castors.
	4. ENERGY SOURCE (Electricity, UPS, Solar, Gas, Water, CO_2....)	
4.1	**Voltage (value, AC or DC, monophase or triphase)**	220 to 240V, 50 Hz
4.2	**Battery operated**	Battery charger to be integral to mains power supply, and to charge battery during mains power operation of unit.Electrical protection by resettable overcurrent breakers or replaceable fuses, fitted in both live and neutral lines. Battery backup of 2 hours for equipment operation. The battery should be protected from overcharging.

4.3	**Tolerance (to variations, shutdowns)**	Voltage corrector / stabilizer to allow operation at ± 30% of local rated voltage.
4.4	**Protection**	Internal, replaceable, rechargeable battery allows operation for at least two hours in the event of power failure.
4.5	**Power consumption**	
4.6	**Other energy supplies**	Mains cable to be at least 3m length.
	5 ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories (mandatory, standard, optional)**	With washable and removable straps and binders.
5.2	**Spare parts (main ones)**	Two extra sets of all sensors.
5.3	**Consumables / reagents (open, closed system)**	Two extra sets of fliters, two extra set of fuses (if replacable fuses used).
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Operating condition: – Capable of operating continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90% in ideal circumstances. – an ambient air velocity is less than 0.3 m/s.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Unit layout to enable easy cleaning and sterilization of all surfaces, with no unreachable fluid traps.The case is to be cleanable with alcohol or chlorine wipes.
6.3	**Others**	
	7. STANDARDS AND SAFETY	
7.1	**Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type); Local and/or international**	Should be FDA / CE approved product Manufacturer / supplier should have ISO 13485 certificate for quality standard. Electrical safety conforms to standards for electrical safety IEC-60601-1. Shall meet IEC-60601-1-2 (General requirements for safety - electromagnetic compatibility) Shall comply with IEC 60601-2-20 transport incubator standard requirement.
	8. TRAINING AND INSTALLATION	
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	Supplier to perform installation, safety and operation checks before handover.
8.2	**Requirements for sign-off**	Certificate of Calibration and inspection from the factory.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided.
	9. WARRANTY AND MAINTENANCE	
9.1	**Warranty**	3 years
9.2	**Maintenance tasks**	Advanced maintenance tasks required shall be documented.
9.3	**Service contract clauses, including prices**	Local clinical staff to affirm completion of installation.
	10. DOCUMENTATION	
10.1	**Operating manuals, service manuals, other manuals**	User, technical and maintenance manuals to be supplied in english language. Certificate of calibration and inspection to be provided. List to be provided of equipment and procedures required for local calibration and routine maintenance List to be provided of important spares and accessories, with their part numbers and cost.
10.2	**Other accompanying documents**	User/Technical/Maintenance manuals to be supplied in English
	11. NOTES	
11.1	**Other information**	Any Contract (AMC/MC/add-hoc) to be declared by the manufacturer
11.2	**Recommendations or warnings**	Any recommendations for best use and supplimentary warning for safety should be declared

BILIRUBINOMETER

Version no. :		1.0
Date:		13/08/13
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Bilirubin measuring device
GMDN code(s)		CT 834
Definition		A laboratory instrument designed to determine, by direct or indirect measurement, the concentration of bilirubin in the blood or other clinical specimen most commonly to rapidly assess hyperbilirubinemia in neonates. It typically performs the measurement using spectrophotometry or haemofluorometry.
1. GENERAL		
1.1	**Clinical purpose**	Determining the concentration of bilirubin in the blood or other clinical specimen, most commonly to rapidly assess hyperbilirubinemia in neonates.
1.2	**Clinical department/ward**	Obstetrics / Neonatal care / NICU.
1.4	**Overview of functional requirements**	1. Measures bilirubin concentration in a blood sample. 2. Displays total bilirubin concentration (conjugated bilirubin level is optional).
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics**	1. Sample volume of < 100 µL required, automatic calibration facility. 2. Total bilirubin concentration measurable (at least) in range of 0 to 20 mg/dl. 3. Time for total concentration measurement: ≤ 5 seconds.
2.3	**Settings**	Method to recalibrate / save current calibration, set sample size.
2.4	**User's interface**	Backlit display with easy viewing in all ambient light levels.
2.5	**Software and/or standard of communication**	Electronic.
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	Approx. 110 x 150 x 200 mm.
3.2	**Weight (lbs, kg)**	5 kg - 15 kgs.
3.3	**Configuration**	(Ex : Compact, modular, to be fixed to walls, ceiling, etc.).
3.4	**Noise (in dBA)**	<60dB.
3.5	**heat dissipation**	heat disbursed through a exhaust fan.
3.6	**Mobility, portability**	Easy and safe transport to be possible by hand, stable when tabletop mounted.
4. ENERGY SOURCE (Electricity, UPS, Solar, Gas, Water, CO_2....)		
4.1	**Voltage (value, AC or DC, monophase or triphase)**	220 to 240V, 50 Hz
4.2	**Battery operated**	NA
4.3	**Tolerance (to variations, shutdowns)**	Voltage corrector / stabilizer to allow operation at ± 30% of local rated voltage, Electrical protection by resettable overcurrent breakers or replaceable fuses fitted in both live and neutral lines.

4.4	**Protection**	(Ex : Resettable overcurrent mains fuse to be incorporated).
4.5	**Power consumption**	
4.6	**Other energy supplies**	Means cable to be at least 3 m in length
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories (mandatory, standard, optional)**	Hard and splashproof case to be supplied.
5.2	**Spare parts (main ones)**	Two sets of spare/replaceable fuses, reagents and capillary tubes sufficient for 100 tests.
5.3	**Consumables / reagents (open, closed system)**	Capillary tubes, haemofluorometric reagents (e.g., aqueous cyanide salt with stabilizers, if applicable).
5.4	**Others**	
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Operating condition: – Capable of operating continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	The case is to be cleanable with alcohol or chlorine wipes.
	7. STANDARDS AND SAFETY	
7.1	**Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type); Local and/or international**	Should be FDA / CE approved product Manufacturer / supplier should have ISO 13485 certificate for quality standard. Electrical safety conforms to standards for electrical safety IEC-60601-1. Shall meet IEC-60601-1-2 (General requirements for safety - electromagnetic compatibility).
	8. TRAINING AND INSTALLATION	
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	Supplier to perform installation, safety and operation checks before handover.
8.2	**Requirements for sign-off**	Local clinical staff to affirm completion of installation.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided.
8.4	**Others**	
	9. WARRANTY AND MAINTENANCE	
9.1	**Warranty**	3 years
9.2	**Maintenance tasks**	Advanced maintenance tasks required shall be documented.
9.3	**Service contract clauses, including prices**	Local clinical staff to affirm completion of installation.
9.4	**Others**	Advanced maintenance tasks required shall be documented.
	10. DOCUMENTATION	
10.1	**Manuals**	User, technical and maintenance manuals to be supplied in english language; List to be provided of equipment and procedures required for local calibration and routine maintenance; List to be provided of important spares and accessories with their part numbers and cost.
10.2	**Other accompanying documents**	User/Technical/Maintenance manuals to be supplied in English.
	11. NOTES	
11.1	**Other information**	Any Contract (AMC/MC/add-hoc) to be declared by the manufacturer.
11.2	**Recommendations or Warnings**	Any recommendations for best use and supplimentary warning for safety should be declared.

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